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WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Original date: July 5, 2005
Revised date: September 8, 2005

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 82552-R, Concrobium
DP Barcode: 318258

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

[Signature] 9/8/05

Thru: Nancy Whyte, Acting Team Leader *NW 9/8/05*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward PM 34/ Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510C)

Applicant: Siamons International, Inc.
Toronto, ON M9W 1A4

Formulation from Label

Active Ingredient(s)	% by wt.
[REDACTED]	[REDACTED]
Other Ingredient(s)	
Total	100.00%

Inert ingredient information may be entitled to confidential treatment

I BACKGROUND

The product, Concrobium (EPA Reg. No. 82552-R), is a new product. The applicant requested to register the product as a fungistat designed to prevent and inhibit growth of mold, fungus and mildew on floors, walls, and other hard nonporous interior building surfaces, until the cause of such growth is identified. Per the proposed label, "this product should be used in those cases where **visible microbial growth** has been detected (or conditions are likely to immediately result in such growth) as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. "As current guidance directs, claims of this nature are considered non-public health. Therefore, efficacy data is reviewed and maintained on file; however performance standards are silent governing acceptance or rejection of efficacy data. Studies were conducted at umedik, Inc., located at 36 Meteor Drive, Toronto, Ontario, Canada, M9W 1A4.

This data package contained a letter from the applicant to EPA (dated May 27, 2005), two efficacy (MRID No. 465589-11 and -12), an Efficacy Discussion (MRID No. 465589-10), and the proposed label. A revised proposed label was submitted to replace previous label submission.

Note— Efficacy testing was not conducted under the framework of 40 CFR 160. An explanation was provided from the registrants detailing study/guideline deviations. According to the document, "...all aspects of GLP were in compliance during both studies [MRID No. 465589-11 and 465589-12] with the exception of 40 CFR Part 160.35 Quality Assurance Unit (QAU)."

II USE DIRECTIONS

This product is designed for use on floors, walls, and other **hard, nonporous** interior surfaces in basements, bathrooms, vacation homes, boat interiors, and areas under construction. Directions on the proposed label provided the following information regarding the use of the product:

Concrobium can be applied by hand-spray, paintbrush, roller, immersion, airless sprayer or pressure fogger (approximately 400 square feet per gallon). To maintain protection against regrowth, do not rinse or wash surfaces after treatment. Re-application of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Preventive Treatment— To inhibit the growth of mold and mildew on surfaces: (1) Apply Concrobium on area until evenly wet; (2) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness; (3) Allow treated surfaces to dry completely.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health do not require efficacy data. However, adequate dosage recommendations and complete directions for use must be provided on product label. These Agency standards are presented in DIS/TSS-16.

IV COMMENTS ON SUBMITTED EFFICACY STUDIES

1. MRID No. 465589-11, "Fabric Mildew Fungistatic Test" for Siamons Mold Control, by Peter Lea, PhD. Study conducted at umedik, Inc. Study completion date— not disclosed. Experimental End Date— August 9, 2004.

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Three lots were (Lot Nos. JJ040113-01/01/01, JJ040210-01/01/01, and JJ040628-01/01/02) of the product Siamons Mold Control were tested according to the test method as published in EPA's Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 1: Fabric Mildew Fungistatic Test Method, November 1982). Two lots (JJ040113-01/01/01 and JJ040210-01/01/01) were designated as the aged products (i.e., ≥60 days old). The product was received ready-to-use. The fungi were inoculated from stock cultures onto neopeptone agar plates and incubated at 25°C for eight days. Upon maturity, the spores were removed, and the suspensions were filtered through sterile cotton to remove the hyphae and hyphal fragments. Strips measuring 25 x 75 mm each were cut from unbleached cotton fabric. Each strip weighed ~ 0.27 grams (143.99 g/m²) to conform to the EPA guidelines. All strips were autoclaved, with a subsequent soak in glycerol nutrient solution for 3 minutes. Each fabric strip was dried under sterile conditions before use. Ten dried, nutrient saturated fabric strips per lot were evaluated. Using a spray bottle, each lot of Siamons Mold Control was sprayed 4 to 5 times on both sides, from a distance of 6-8 inches, onto the fabric strips. The strips were hung in the sterile laminar air flow hood. Ten untreated fabric strips were sprayed with saline solution in place of the test agent for the untreated control. All samples were allowed to dry before inoculation. Equal volumes of 5×10^6 conidia/ml suspension of *A. niger* and *P. variable* were mixed together and agitated. Each side of each fabric strips was lightly sprayed to inoculate the mixed conidial suspension using a DeVilbiss atomizer. The fabric samples were suspended in individual 500 ml jars containing approximately 90 ml sterile water, and incubated at 28±2°C. Observations were made and recorded weekly for 4 weeks (minimally 7, 14, 21 and 28 days). The presence or absence of observable mold on the fabric strips was the criterion for determining the efficacy of the test agent. When no visible growth was evident at the end of the test period, the fabric strips were examined microscopically. Controls included those for purity and sterility.

Note— According to MRID No. 465589-10, Siamons Mold Control is identical to Concrobium, the subject of the current efficacy review.

2. MRID No. 465589-12, "Hard Surface Mildew Fungistatic Test" for Siamons Mold Control, by Peter Lea, PhD. Study conducted at umedik, Inc. Study completion date— not disclosed. Experimental end date— July 16, 2004.

The study was conducted against *Aspergillus niger* (ATCC 6275). Three lots (Lot Nos. JJ040113-01/01/01, JJ040210-01/01/01, and JJ0404628-01/01/02) of the product, Siamons Mold Control, were tested using the were tested according to the method published in Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 2: Hard Surface Mildew Fungistatic Test Method, November 1982). Two lots (JJ040113-01/01/01 and JJ040210-01/01/01) were designated as the aged products (i.e., ≥ 60 days old). The product was received ready-to-use. *A. niger* was inoculated from stock cultures onto neopeptone agar plates and incubated at $25 \pm 2^\circ\text{C}$ for eight days. Upon maturity, the spores were removed and the suspensions were filtered through sterile cotton to remove hyphae and hyphal fragments. Ten carriers (glazed ceramic tiles) per lot were sprayed with the test substance using a spray bottle. Each tile was sprayed 4 to 5 times to ensure complete wetting. The distance from the nozzle of the spray bottle to a tile was 10 centimeters. Post spraying, the carriers were placed in a vertical or near vertical position in a separate Petri dish to permit excess liquid to drain. Five tiles were placed in each of two sterile Petri dishes with lids ajar and allowed to dry for 30 minutes at 37°C . Ten untreated tiles were placed in Petri dishes with lids ajar and allowed to dry at 37°C . Glazed ceramic carriers were inoculated with a 5.0×10^6 conidia/ml, utilizing a #152 DeVilbiss atomizer while maintaining agitation. The tiles, located in Petri dishes, were returned to 37°C incubator and dried for 30 minutes until visibly dry. Carriers were subsequently placed in individual Petri dished containing harden sterile water agar for 7 days at $25 \pm 2^\circ\text{C}$ with 95% humidity. Post incubation, the plates were observed for the presence or absence of macroscopic fungal growth. If no visible growth was evident at the end of the test period, the carrier was examined microscopically. Control included those for purity and sterility.

Note— According to MRID No. 4655589-10, Siamons Mold Control is identical to Concrobium, the subject of this current efficacy review.

V RESULTS

Siamons Mold Control, Lot No. JJ040113-01/01/01 (>60 days old)

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0×10^6
	<i>P. variable</i>						5.1×10^6

Note– Untreated control 100% visual growth on carrier.

Saimons Mold Control, Lot JJ040210-01/01/01 (60 days old)

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0×10^6
	<i>P. variable</i>						5.1×10^6

Note– Untreated control 100% visual growth on carrier.

Siamons Mold Control, Lot JJ040628-01/01/02

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0×10^6
	<i>P. variable</i>						5.1×10^6

Note– Untreated control 100% visual growth on carrier.

MRID Number	Organism	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			7 Days Exposure				
			JJ040112-01/01/01	JJ040210-01/01/01	JJ040628-01/01/02	Control	
465589-12	<i>A. niger</i>	1-10	0%	0%	0%	100%	5.0 x 10 ⁶

VI CONCLUSIONS

1. The submitted efficacy data (MRID 465589-11) **support** the use of the product, Siamons Mold Control (ready-to-use), as a fungistat/mildewstat against *Aspergillus niger* and *Penicillium variable* on surfaces composed of fabric in the absence of a soil load for a period of extended wetness. The study was not conducted according to GLP guidelines/recommendations (40 CFR 160), however the study deviation, in this case, was not significant.
2. The submitted efficacy data (MRID 465589-12) **support** the use of the product, Siamons Mold Control (ready-to-use), as a fungistat/mildewstat against *Aspergillus niger* on hard, non-porous surfaces in the absence of soil for a period of extended wetness. The study was not conducted according to GLP guidelines/recommendations (40 CFR 160), however the study deviation, in this case, was not significant.

VII LABEL COMMENTS/RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of, Concrobium, as an effective fungistat/mildewstat on hard, non-porous surfaces in the absence of soil when applied for a period of "extended wetness". Re-application directions, as requested, were included on the revised label.
2. On the revised proposed label (under Reapplication section) determine whether "re-application" or "reapplication" will be used, for consistency.